

## USER FEE OBLIGATIONS

User fees may be expended only for costs necessary to support the process for the review of human drug applications, as defined in PDUFA. Allowable and excludable costs for the process for the review of human drug applications are described in Appendix C.

In FY 2013, FDA obligated \$666,901,600 from prescription drug user fees. Table 2 provides a breakout of user fee obligations by expense category during the past two fiscal years.

**TABLE 2: PRESCRIPTION DRUG USER FEE OBLIGATIONS BY EXPENSE CATEGORY AS OF SEPTEMBER 30, 2012 AND SEPTEMBER 30, 2013**

EXPENSE CATEGORY	FY 2012	FY 2013
Personnel Compensation and Benefits	\$417,261,313	\$435,684,523
Travel and Transportation	\$6,527,641	\$4,936,201
Rent	\$18,741,600	\$23,574,700
Communications	\$9,179,407	\$9,660,391
Contract Services	\$171,262,538	\$171,499,086
Equipment and Supplies	\$13,420,863	\$15,851,593
Other <sup>1</sup>	\$535,439	\$5,695,106
<b>TOTAL OBLIGATIONS</b>	<b>\$636,928,801</b>	<b>\$666,901,600</b>

<sup>1</sup>Other includes expenses from categories such as rent payments to others, printing & reproduction, grants, and other miscellaneous expenses.

FDA dedicated 1,277 FTEs to the process for the review of human drug applications in FY 1992, before PDUFA was enacted. In FY 2013, PDUFA fees and appropriations paid for a total of 3,655 FTEs; an increase of 2,378 FTEs over FY 1992 levels for the review process. Employee salary and benefits paid from user fees in FY 2013 totaled approximately 65 percent of the obligations from fees.

Table 3 below provides additional information on FDA's IT obligations for the process for the review of human drug applications. The table highlights IT obligations for Center IT systems and IT systems that are common across the organizations participating in the human drug review process. For each of these expense categories, FDA's IT spending is further itemized by funding source, PDUFA user fee or congressional appropriation (S&E), and purpose, systems development or maintenance.

**TABLE 3: FY 2013 IT OBLIGATIONS BY IT CATEGORY AND FUNDING SOURCE AS OF SEPTEMBER 30, 2013**

<b>IT EXPENSE CATEGORY</b>	<b>S&amp;E</b>	<b>PDUFA</b>	<b>Total</b>	<b>Development</b>	<b>Maintenance</b>
Center IT Systems	\$6,402,244	\$9,238,931	\$15,641,175	\$4,370,642	\$11,270,533
Common IT Systems <sup>1</sup>	\$17,148,148	\$40,761,038	\$57,909,186	\$15,269,894	\$42,639,292
<b>TOTAL OBLIGATIONS</b>	<b>\$23,550,392</b>	<b>\$49,999,969</b>	<b>\$73,550,361</b>	<b>\$19,640,536</b>	<b>\$53,909,825</b>

<sup>1</sup> IT systems common across organizational divisions participating in the process for the review of human drug applications

See the section entitled, TOTAL COSTS OF THE PROCESS FOR THE REVIEW OF HUMAN DRUG APPLICATIONS, on page 11, for more discussion on the total human drug review process costs.